FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Guatemala	**Agency Name:** Ministerio de Salud Pública y Asistencia Social (MSPAS)	
Name of FRP: Procedure for the recognition of sanitary registration of medicines.		
Is this FRP Proposed or Active? Choose an item.		
Date FRP was officially enacted: Click here to enter a date.		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☐	☐

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	Choose an item.
Does the agency provide assistance/advice to the sponsor?	Choose an item.
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	Click here to enter text.
Must the product address an unmet medical need or serious condition?	Choose an item.
If a fee is required, what is the amount (in US$ equivalent)	[GUIDELINE IN SPANISH] Tariff for services provided by the departments of the General Directorate of Regulation, Surveillance and Health Control, June 8, 2006, Published in the Journal of Central America on June 19, 2006. https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=9%3Aag-297-2006
Total target (agency) time for assessment (calendar days)	Click here to enter text.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

Select one of the following (* see definitions at end of document)

Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**
☐	☐	☐

If this is a reliance or recognition pathway, what	Click here to enter text.

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are the accepted reference agencies?	
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Click here to enter text.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Choose an item.
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	
Date of this update	26 APRIL 2020
References	The documents and official guidelines are in Spanish on the NMRA's website: 1. Reforms to Governmental Agreement 712-99 dated September 17, 1999, Regulations for the Sanitary Control of Medicines and Related Products. https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=1%3Aag-351-2006 Accessed on 26 April 2020. 2. Regulation for the Sanitary Control of Medicines and Related Products.

https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=7%3Aag-712-99 Accessed on 26 April 2020.

3. Tariff for services provided by the departments of the General Directorate of Regulation, Surveillance and Health Control, June 8, 2006, Published in the Journal of Central America on June 19, 2006. https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=9%3Aag-297-2006 Accessed on 26 April 2020.
4. Annex 1 of resolution no. 93-2002 (COMIECO-XXIV) procedure for the mutual recognition of sanitary registration of medicines with sanitary registration prior to the entry into force of the customs union for member countries. https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos?download=231%3Aac-506-2002&start=20 Accessed on 26 April 2020.
5. ***Recognition of sanitary registration of drugs approved by regulatory agencies level IV according to the Pan American Health Organization (PAHO) as a basis for processing registration approval in Guatemala. 07-19-2018.** https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/normas-tecnicas?download=285%3Anorma-tecnica-077-2018 Accessed on 26 April 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.